

## **REMARKS**

### **Summary**

Claims 1-4, 6-9, and 20-28 are pending. Claim 1 is amended herein. No new matter is added.

### **Objection to the Specification**

The specification has been objected to for not containing support for the subject matter of original claim 16. In response, Applicants have amended the specification to clarify and recite the subject matter presented in claim 16, and otherwise supported by the present specification and figures. No new matter is added.

### **102(b) Rejection of Claims 1-4 and 6-9**

Claims 1-4 and 6-9 are rejected under 35 USC 102(b) as being unpatentable over US Patent No. 4,703,756 to Gough (Gough '756). Applicants respectfully traverse the rejection in light of the amendments to the claims and the remarks below.

Claim 1 recites an indwelling analyte sensor, comprising an electrochemically active surface; at least one nub of dielectric material extending outwardly from said electrochemically active surface; and a membrane system adhering to, and surrounding, said electrochemically active surface and said nub. Gough '756 fails to teach or suggest every element of claim 1.

Gough '756 provides a sensor module having a housing within which is housed electrodes partially encased in glass. Despite the assertion of the Office Action that element 14 of Gough '756 is part of a membrane system, element 14 refers to the catheter housing, which is specifically distinguished in the reference from the membranes 20 and 22. At the terminal portion of the glass casings, may be found a hydrophobic membrane 20. In addition, at the terminal portion of the hydrophobic membrane may be found a glucose oxidase – albumin membrane 22.

However, nowhere in Gough '756 is there a teaching or suggestion of a membrane system adhering to, and surrounding, both an electrochemically active surface and a nub. As is clearly shown in Figures 3, 4, and 5 of Gough '756, the two

membranes discussed are only located at the terminal end of the electrodes and the tip of the insulating material, and thus do not surround both the electrochemically active surface and a nub. Applicants' clarification of this feature is fully supported by the description and the figures of the present application. In particular, Figures 1 and 2 show a membrane surrounding both the electrochemically active surface and the nubs, which is quite different from the end-cap arrangement provided in Gough '756.

Thus, Gough '756 fails to teach at least one feature of claim 1, and therefore, claim 1 is patentable over Gough '756.

Claims 2-4 and 6-9 depend directly or indirectly on claim 1, incorporating the features of claim 1. Therefore, as claim 1 is patentable over Gough '756, so are claims 2-4 and 6-9 by virtue of at least their dependency.

#### **102(b) Rejection of Claims 1-4, 6-9, 20-21, and 24**

Claims 1-4, 6-9, 20-21, and 24 are rejected under 35 USC 102(b) as being unpatentable over US Patent No. 4,671,288 to Gough (Gough '288). Applicants respectfully traverse the rejection in light of the amendments to the claims and the remarks below.

Claim 1 recites an indwelling analyte sensor, comprising an electrochemically active surface; at least one nub of dielectric material extending outwardly from said electrochemically active surface; and a membrane system adhering to, and surrounding, said electrochemically active surface and said nub. Gough '288 fails to teach or suggest every element of claim 1.

Gough '288 provides a sensor module having a housing with one or more openings that may be in fluid communication with biological fluids. Membrane 24 may be applied at the opening(s) and may be used to control the permeation of glucose and oxygen. Gough '288 also includes an electrode 18 and various dielectric regions 27.

However, nowhere in Gough '288 is there a teaching or suggestion of a membrane system adhering to, and surrounding, both an electrochemically active surface and a nub. As is clearly shown in Figures 1-9 of Gough '288, at no point does a membrane surround both the electrochemically active surface and a nub. Applicants'

clarification of this feature is fully supported by the description and the figures of the present application. In particular, Figures 1 and 2 show a membrane surrounding both the electrochemically active surface and a nub, which is quite different from the arrangement provided in Gough '288.

Thus, Gough '288 fails to teach at least one feature of claim 1, and therefore, claim 1 is patentable over Gough '288.

Claims 2-4, 6-9, 20-21, and 24 depend directly or indirectly on claim 1, incorporating the features of claim 1. Therefore, as claim 1 is patentable over Gough '288, so are claims 2-4, 6-9, 20-21, and 24 by virtue of at least their dependency.

### **103(a) Rejection of Claims 22, 23, and 25**

Claims 22, 23, and 25 are rejected under 35 USC 103(a) as being unpatentable over Gough '288. Applicants respectfully traverse the rejection in light of the amendments to the claims and the remarks below.

Claims 22, 23, and 25 depend directly or indirectly on claim 1, incorporating the features of claim 1. Therefore, as claim 1 is patentable over Gough '288, so are claims 22, 23, and 25 by virtue of at least their dependency.

In particular with respect to claims 22 and 23, the Office Action indicates that claims 22 and 23 are rejected over Gough '288, apparently despite the fact that there is no similar teaching or suggestion in Gough '288, because the shape of the membrane system is not stated to be for a particular purpose. Applicants respectfully disagree. The combination of a nub extending outward from an electrochemically active surface and a membrane system applied thereto, provides for the shape characteristics recited in claims 22 and 23. The benefit of such shapes are described in the specification beginning at page 3, line 4, in which it is stated that "[t]he surface of each viscous fluid tends to form a shape somewhat like a catenary curve between plates 22. Accordingly a greater portion of viscous fluid adheres than would adhere without the presence of plates 22. This greater thickness, especially for glucose oxidase layer is very important in the creation of a robust response to the presence of glucose and oxygen."

Thus, utilizing the physical structures defined in the claims, the membrane is concentrated at the electrochemically active surface between the plurality of nubs. In addition, the defined shapes are a product of a relatively inexpensive process (i.e., dip coating) as compared to other deposition methods, and thus are beneficial in bringing about the desired effect of membrane loading without increasing cost.

#### **103(a) Rejection of Claim 26**

Claim 26 is rejected under 35 USC 103(a) as being unpatentable over Gough '288 in view of US Patent No. 6,144,871 to Saitoh et al. (Saitoh). Applicants respectfully traverse the rejection in light of the amendments to the claims and the remarks below.

Claim 26 depends on claim 1, incorporating the features of claim 1. Therefore, as claim 1 is patentable over Gough '288, so is claim 26 by virtue of at least its dependency. Saitoh fails to overcome the deficiencies of Gough '288 discussed above. Thus, claim 26 is patentable over Gough '288 and Saitoh for at least the reasons discussed above with respect to claim 1.

#### **103(a) Rejection of Claims 27 and 28**

Claims 27 and 28 are rejected under 35 USC 103(a) as being unpatentable over Gough '288 in view of US Patent No. 5,165,407 to Wilson (Wilson). Applicants respectfully traverse the rejection in light of the amendments to the claims and the remarks below.

Claims 27 and 28 depend indirectly on claim 1, incorporating the features of claim 1. Therefore, as claim 1 is patentable over Gough '288, so are claims 27 and 28 by virtue of at least their dependency. Wilson fails to overcome the deficiencies of Gough '288 discussed above. Thus, claims 27 and 28 are patentable over Gough '288 and Wilson for at least the reasons discussed above with respect to claim 1.


**Conclusion**

In view of the foregoing, Applicant respectfully submits that claims 1-4, 6-9, and 20-28 are in condition for allowance, and early issuance of the Notice of Allowance is respectfully requested.

If the Examiner has any questions, he is invited to contact the undersigned at (503) 796-2844. Please charge any shortages and credit any overages to Deposit Account No. 500393.

Respectfully submitted,  
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